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SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

Attorney Docket No.

06132/041002

Serial No.

09/881,752

Applicant

Harold Kleanthous et al.

Filing Date

June 18, 2001

Group

Not Yet Assigned

IDS Filed

October 17, 2001

Customer No.

21559

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use several sheets if necessary)

(37 C.F.R. §1.98(b))

U.S. PATENTS

| Examiner's Initials | Patent Number | Issue Date | Patentee | Class | Subclass | Filing Date (If Appropriate) |
|------------------------|---------------|------------|--------------------|-------|----------|---------------------------------|
| V80 | 5,116,821 | 05/26/92 | Randall et al. | | | |
| | 5,128,140 | 07/07/92 | Chapura et al. | | | |
| | 5,258,178 | 11/02/93 | Cordle et al. | | | |
| | 5,447,923 | 09/05/95 | Catrenich et al. | | | |
| | 5,476,669 | 12/19/95 | Borody | | | |
| | 5,538,729 | 7/23/96 | Czinn | | | |
| | 5,514,660 | 05/07/96 | Zopf et al. | | | |
| | 5,563,039 | 10/08/96 | Goeddel et al. | | | |
| | 5,567,594 | 10/22/96 | Calenoff | | | |
| | 5,610,060 | 03/11/97 | Ward et al. | | | |
| | 5,620,964 | 04/15/97 | Roth et al. | | | |
| | 5,676,950 | 10/14/97 | Small, Jr. et al. | | | |
| | 5,679,769 | 10/21/97 | Danishefsky et al. | | | |
| | 5,753,630 | 05/19/98 | Zopf et al. | | | |
| * | 5,837,240 | 11/17/98 | Lee et al. | | | |
| * | 5,972,336 | 10/26/99 | Michetti et al. | | | |
| * | 6,290,962 B1 | 09/18/01 | Michetti et al. | | | |

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DATE CONSIDERED

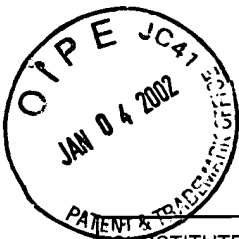
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FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

| Examiner's Initials | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation (Yes/No) |
|---------------------|-----------------|------------------|--------------------------|-------|----------|----------------------|
| VBP | WO 91/09049 | 27.06.91 | PCT | | | |
| | WO 93/18150 | 16.09.93 | PCT | | | |
| | WO 94/09823 | 11.05.94 | PCT | | | |
| | WO 95/22987 | 31.08.95 | PCT | | | |
| | WO 95/33482 | 14.12.95 | PCT | | | |
| | WO 96/33732 | 31.10.96 | PCT | | | |
| | WO 97/03359 | 30.01.97 | PCT | | | |
| | WO 97/03360 | 30.01.97 | PCT | | | |
| | WO 97/19098 | 29.05.97 | PCT | | | |
| | WO 97/11182 | 27.03.97 | PCT | | | |
| | WO 97/12908 | 10.04.97 | PCT | | | |
| | WO 97/12909 | 10.04.97 | PCT | | | |
| | WO 97/37044 | 09.10.97 | PCT | | | |
| | WO 97/47646 | 18.12.97 | PCT | | | |
| | WO 98/18323 | 07.05.98 | PCT | | | |
| | WO 96/38475 | 05.12.96 | PCT | | | |
| | WO 96/40893 | 19.12.96 | PCT | | | |
| ✓ | 676,474 | 95 | Europe | | | |
| | JP 07222590 | 95 | Japan | | | |

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OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

| | |
|---|---|
| ✓ | Bazillou et al., "Serum Antibody Response to the Superficial and Released Components of <i>Helicobacter pylori</i> ," Clin. and Diag. Lab. Immun. 1(3):310-317 (1994). |
| | Borén et al., "Attachment of <i>Helicobacter pylori</i> to Human Gastric Epithelium Mediated by Blood Group Antigens," Science 262:1892-1895 (1993). |
| | Borody et al., "Omeprazole enhances efficacy of triple therapy in eradicating <i>Helicobacter pylori</i> ," Gut 37:477-481 (1995). |
| | Bukanov et al., "Ordered Cosmid Library and High-Resolution Physical-Genetic Map of <i>Helicobacter pylori</i> Strain NCTC11638," Mol. Microbiology 11(3):509-523 (1994). |
| | Bult et al., "Complete Genome Sequence of the Methanogenic Archaeon, Methanococcus Jannaschii," Science 273:1058-1073 Abstract (1996). |
| | Clayton et al., "Sensitive Detection of <i>Helicobacter pylori</i> by Using Polymerase Chain Reaction," Journal of Clinical Microbiology 30:192-200 (1992). |
| | Czinn et al., "Oral immunization against <i>Helicobacter pylori</i> ," Infection and Immunity 59:2359-2363 (1991). |
| | D'Ellos et al., "T Helper 1 Effector Cells Specific for <i>Helicobacter pylori</i> in the Gastric Antrum of Patients with Peptic Ulcer Disease," The Journal of Immunology 158:962-967 (1997). |
| | Doig et al., "Identification of Surface-Exposed Outer Membrane Antigens of <i>Helicobacter pylori</i> ," Infection and Immunity 62:4526-4533 (1994). |
| | Drouet et al., "Partial Characterization of an External Polysaccharide of <i>Helicobacter pylori</i> by Using an Immunoglobulin M Monoclonal Antibody," Infection and Immunity 61:2732-2736 (1993). |
| | Dunkley et al., "Development of an Animal Model to Test a <i>Helicobacter pylori</i> Vaccine," Microbiology Ecol. Health and Disease 4:S148 Abstract (1991). |
| | Farokhnia, "Antibody Specific for a Plasmid-Encoded Protein of <i>Helicobacter Pylori</i> ," Thesis, Grad. School of The Texas Women's University, Department of Biology, p. 1-30. |
| | Fauchere et al., "Adherence of <i>Helicobacter pylori</i> Cells and Their Surface Components to HeLa Cell Membranes," Microbial Pathogenesis 9:427-439 (1990). |
| | Ferrero et al., "Recombinant Antigens Prepared from the Urease Subunits of <i>Helicobacter</i> spp.: Evidence of Protection in a Mouse Model of Gastric Infection," Infection and Immunity 62:4981-4989 (1994). |
| | Graham et al., "Effect of Triple Therapy (Antibiotics plus Bismuth) on Duodenal Ulcer Healing," Annals of Internal Medicine 115:266-269 (1991). |
| ✓ | Haas et al., "TnMax - a versatile mini-transposon for the analysis of cloned genes and shuttle mutagenesis," Gene 130:23-31 (1993). |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

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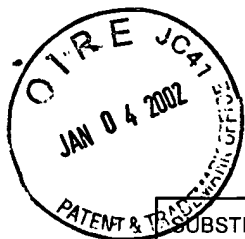
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

| | |
|---|---|
| ✓ | Heap et al., "Immunisation and Gastric Colonisation with <i>Helicobacter Felis</i> ," Microb. Ecol. Health and Disease 4:S118 Abstract (1994). |
| ✓ | Husson et al., "Iron Acquisition by <i>Helicobacter pylori</i> : Importance of Human Lactoferrin," Infection and Immunity 61:2694-2697 (1993). |
| ✓ | Illingworth et al., "Siderophore Production and Iron-regulated Envelope Proteins of <i>Helicobacter pylori</i> ," Zbl. Bakt. 280:113-119 (1993). |
| ✓ | Kaplan, "Autogenous Vaccination Against <i>Helicobacter pylori</i> ," South African Medical Journal 83:922-92 (1993). |
| ✓ | Lee et al., "Oral immunization with recombinant <i>Helicobacter pylori</i> urease induces secretory IgA antibodies and protects mice from challenge with <i>Helicobacter felis</i> ", The Journal of Infectious Diseases 172:161-172 (1995). |
| ✓ | Mohammadi et al., " <i>Helicobacter</i> -Specific Cell-Mediated Immune Responses Display a Predominant Th1 Phenotype and Promote a Delayed-Type Hypersensitivity Response in the Stomachs of Mice," The Journal of Immunology 156:4729-4738 (1996). |
| ✓ | Monath et al., "Progress Towards a Vaccine Against <i>Helicobacter pylori</i> ," American J. Gastroenterology 89:1393 Abstract (1994). |
| ✓ | Monath et al., "Development of Recombinant <i>Helicobacter pylori</i> Urease as an Oral Vaccine: Current Status," Gut 37 (Suppl. 1):A52, 205 (1995). |
| ✓ | Myers et al., "Oral Immunization with Recombinant Urease Confers Long-Lasting Immunity," Gut 39 (Suppl. 2):A44, 1B:24 (1996). |
| ✓ | Nakao et al., "Antibacterial Properties of Lansoprazole Alone and in Combination with Antimicrobial Agents against <i>Helicobacter pylori</i> ," Eur. J. Clin. Microbiol. Infect. Dis. 14:391-399 (1995). |
| ✓ | Robinson et al., "Protection against a lethal influenza virus challenge by immunization with a haemagglutinin-expressing plasmid DNA", Vaccine 11:957-960 (1993). |
| ✓ | Robinson et al., "Use of direct DNA inoculations to elicit protective immune responses", Vaccines 93, "Use of Direct DNA Inoculations to Elicit Protective Immune Responses," Cold Spring Harbor Laboratory Press, 311-315 (1993). |
| ✓ | Sherburne et al., " <i>Helicobacter pylori</i> Expresses a Complex Surface Carbohydrate, Lewis X," Infection and Immunity 63:4564-4568 (1995). |
| ✓ | Taylor et al., "Construction of a <i>Helicobacter pylori</i> Genome Map and Demonstration of Diversity at the Genome Level," J. Bacteriol. 174(21):6800-6806 (1992). |
| ✓ | Thijs et al., "Efficacy and Side Effects of a Triple Drug Regimen for the Eradication of <i>Helicobacter pylori</i> ," Scand. J. Gastroenterol. 28:934-938 (1993). |

EXAMINER

DATE CONSIDERED

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|---|---|
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| | OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) |
| | Tomb et al., "The Complete Genome Sequence of the Gastric Pathogen <i>Helicobacter pylori</i> ," Nature 388:539-547 (1997). |
| | Ulmer et al., "Heterologous protection against influenza by injection of DNA encoding a viral protein", Science 259:1745-1749 (1993). |
| | Wadstrom, "Microbial Adhesion: New Concepts for Development of Antiadhesion Strategies to Combat Bacterial Infections," Acta Microbiologica Hungarica 38:164-165 (1991). |
| | Wilson et al., "2.2 Mb of Contiguous Nucleotide Sequence from Chromosome III of <i>C. elegans</i> ," Nature 368:32-38 Abstract (1994). |
| | Haas et al., U.S. Serial No. 08/749,051, filed 11/14/96. |
| | Haas et al., U.S. Serial No. 08/831,309, filed 4/1/97. |
| | Haas et al., U.S. Serial No. 08/834,705, filed 4/1/97. |
| | Kleanthous et al., U.S. Serial No. 09/831,310, filed 4/1/07. |
| | Kleanthous et al., U.S. Serial No. 09/881,752, filed 6/18/01. |
| | Kleanthous et al., U.S. Serial No. 08/834,666, filed 4/1/97. |
| | Kleanthous et al., U.S. Serial No. 09/882,227, filed 6/15/01. |
| | Lee et al., U.S. Serial No. 08/568,122, filed 12/6/95. |
| Michetti et al., U.S. Serial No. 09/426,328, filed 10/25/99. | |
| Michetti et al., U.S. Serial No. 09/955,739, filed 9/18/01. | |
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